

# Biostatistics Unit

**Dr. Lehana Thabane – Director**

## Introduction

The primary aim of the Biostatistics Unit is to provide comprehensive, flexible and timely statistical support tailored to the ongoing needs of researchers at the Programs for Assessment of Technology in Health (PATH) and the Centre for Evaluation of Medicines (CEM), at St. Joseph's Healthcare Hamilton, and at the Faculty of Health Sciences at McMaster University.

The Biostatistics Unit aims to provide continuous help with routine and state-of-the-art statistical methods at various stages of the research process: planning, implementation, analysis and reporting.

## Development

The Biostatistical Unit at St. Joseph's Healthcare Hamilton was formed in early 1995 when Dr. C.H. Goldsmith was appointed Head of Biostatistics. Dr. Goldsmith and his staff began providing biostatistical data management services, statistical analysis, research grant analysis, and consultation services to a variety of researchers through St. Joseph's Healthcare Hamilton as well as McMaster University.

The mandate of the Unit was to continue to be involved in a large spectrum of research projects which included projects associated with McMaster University, in particular the Faculty of Health Sciences, projects extra to McMaster University, projects carried out by faculty members associated with St. Joseph's Healthcare Hamilton, as well as a variety of local, national and international educational ventures. These were not to change in the mix; however, new opportunities were to be pursued, with the primary focus on St. Joseph's Healthcare.

Dr. A.R. Willan joined the Unit in September, 1997, and he brought on a staff person to be associated with his work, currently Dr. Gary Foster. As of July 1, 2002 Dr. Willan is Professor Emeritus in the Department of Clinical Epidemiology and Biostatistics at McMaster University.

Dr. L. Thabane joined the Department of Clinical Epidemiology and Biostatistics at McMaster University and, in particular, the Biostatistical Unit at the Centre for Evaluation of Medicines (CEM), associated with the Father Sean O'Sullivan Research Centre (FSORC), on January 1, 2002.

The Biostatistics Unit has provided a variety of support and consulting services to a broad spectrum of people in the overall community, local health care agencies, health care researchers associated with St. Joseph's Healthcare Hamilton in its broadest context, including the network of St. Joseph's Hospitals, faculty members at McMaster University, and the rest of the University, as well as outside projects. General support services for data entry, data analysis, helping with writing manuscripts, editing of manuscripts and research grants has been a forefront of the Unit. Because of the technical skills required, computer expertise has rested with this Unit and Biostatistics is often called upon to provide support to other researchers at PATH and CEM in particular.

A more detailed outline of the available services is provided below in the summary of the current support services.

While Dr. S.M. MacLeod was Chair of the Research Ethics Board (REB) associated with St. Joseph's Healthcare Hamilton, the REB asked Dr. Goldsmith to become a member as of October 18, 1999. Dr. Goldsmith then further participated in all of the discussions of the Board meetings as well as the Board Subcommittee to evaluate the ethical principles associated with the research projects being conducted at St. Joseph's Healthcare Hamilton. Dr. Goldsmith resigned from the REB Subcommittee at the end of December 2001 and Dr. Thabane came on board as an Observer until Dr. Goldsmith resigned from the main REB Committee at the end of June 2002. Dr. Thabane has taken over as a full Board member since July 1, 2002. Being visible on the REB (now HiREB) has meant that a lot of consultations have come to the Biostatistical Unit from research projects associated with the investigators who brought forward ideas that may have been deficient in issues related to research methodology and biostatistics.

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## **Research Priorities**

The specific aims of the Unit include:

1. Provision of statistical consulting services to researchers at PATH and CEM, St. Joseph's Healthcare, and the Faculty of Health Sciences at McMaster University, including:
  - a. Help with study planning,
  - b. Guidance with data collection methods,
  - c. Assistance with data analysis and interpretation of results, and
  - d. Help with report writing and manuscript preparation.
2. Assistance to promote appropriate practice and application of statistical methods in healthcare research.
3. Provision of statistical support to researchers through collaboration on preparation of grant proposals and guidance on research plans and methodologies.
4. Assistance to enhance proper and ethical application of statistical techniques through participation in reviews of Hamilton integrated Research Ethics Board (HiREB) submissions.
5. Increasing the awareness of the utility of statistical methods in both healthcare research and teaching.

## **Research Goals**

- To support the research goals and objectives of PATH, CEM and CE&B through collaborative participation in research projects taking place at PATH, CEM and CE&B.
- To support the research goals of St. Joseph's Healthcare through collaborative efforts at St. Joseph's Healthcare Hamilton as well as projects taking place in other research hospitals that make up the Hamilton Health Sciences.
- To support the research activities at St. Joseph's Healthcare through collaborative efforts in projects taking place at St. Joseph's Healthcare Hamilton or by providing statistical support/advice as may be required or requested by various researchers within St. Joseph's Healthcare Hamilton.
- To continue to participate in the activities of the HiREB.
- To continue contribute clinical trial or statistical methodology development through independent research.

- To present research findings at professional meetings and at PATH, CEM and CE&B rounds.
- To continue to foster connections with researchers from other institutions nationally and internationally.

## Education

Education forms an integral part of our mandate as a unit within an academic institution. Drs. Thabane and Foster are members of the Department of Clinical Epidemiology and Biostatistics (CE&B), which is the parent department for the Faculty.

Specific education goals of the Unit include:

1. Supporting the Health Research Methodology (HRM) Program through participation in teaching or supervision of graduate students;
2. Supporting the Bachelor of Health Science (BHSc) undergraduate program as instructors;
3. Offering short courses and workshops to researchers:
  - Bayesian methods
  - meta-analysis methods
  - writing workshops
  - statistical consulting
  - multivariate statistical methods

## Services

The Biostatistics Unit provides a wide spectrum of services:

1. Research design to ensure the integrity of the research protocol, including:
  - guidance on preparation of grant proposals;
  - identification of the most efficient design and planning of research studies;
  - assistance with devising effective sampling strategies;
  - help with sample size determination and power calculations; and
  - hypothesis development.
2. Central telephone randomization service:
  - service available 24 hours a day, 7 days a week;
  - methods of randomization available:  
unrestricted: simple randomization  
restricted: block randomization  
stratified randomization;
  - examination of the distributional properties of the sequence prior to first allocation; and
  - full documentation provided.
3. Case Report Form (CRF) design and development:
  - provide assistance designing the CRF;
  - develop and thoroughly test the CRF prior to use; and
  - database designed to accommodate data collected on the CRF.
4. Data management services:
  - data entry  
- completed forms are faxed to a secure computer at the Biostatistics Unit for data entry

- faxed data forms can be received 24 hours a day, 7 days a week
  - data entry usually takes place the next business day
  - data are entered while the original CRF remains at the clinical site (no postage costs, no CRFs get lost in transport, CRFs remain in a secure location, photocopying of CRF is not necessary);
  - o data cleaning
    - query resolution takes place while study is ongoing
    - clean database ensured shortly after study completion; and
  - o periodic data management update reports are provided to investigator.
5. Data analysis using standard statistical techniques and powerful state-of-the-art methods, including:
    - o advice on what software to use;
    - o tabular and graphical representation of data;
    - o analysis using routine and advanced statistical procedures; and
    - o examination of model assumptions through diagnostic tests.
  6. Interpretation of results: interpretation of statistical analyses to enhance communication of the results in a clear, meaningful way, including:
    - o clear descriptions of methods used to analyze the data;
    - o detailed reporting of the analysis results;
    - o assistance with report writing for granting agencies; and
    - o assistance with manuscript preparation.
  7. Short courses and workshops: customized short courses and workshops on various statistical topics, including:
    - o Bayesian methods;
    - o meta-analysis methods;
    - o writing workshops;
    - o statistical consulting; and
    - o multivariate statistical methods.

## Faculty & Research Staff

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